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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/718,388 11/24/00 YAMAMOTO N 001554

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EXAMINER

KATCHERES, K

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

10/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/718,388

Applicant(s)

YAMAMOTO ET AL.

Examiner

Konstantina Katcheves

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 6. 6) ☒ Other: *detailed action*.

DETAILED ACTION

Claims 1-28 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 drawn to a method for proliferating and adhering cells, classified in class 435, subclass 357.
- II. Claims 16-28, drawn to a culture vessel, classified in class 435, subclass 283.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to a method of culturing cells as in group I and a culture vessel as in group II. The claims are separate and distinct inventions because the culture vessel of group II may be used for cells other than those claimed in group I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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During a telephone conversation with William Westerman on or about 10 August 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-13. Claims 14 and 15 have been rejoined with group I for purposes of examination. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Accordingly, claims 1-15 have been examined.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, these inventions have acquired a separate status in the art because of their recognized divergent subject matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 1-16 are objected to because of the following informalities: The claims appear to contain a common grammatical errors. The claims, in addition to the specification, appear to be missing necessary articles before nouns in sentences. Alternatively, some of these nouns could more appropriately be made plural. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The invention of the instant claims is drawn to a method for the adhering and proliferating of cells comprising the inoculating, culturing and killing of fibroblast cells. This method appears to be incomplete because there is no nexus or causal relationship between the steps provided and the preamble of the claim. It is not apparent how one of skill in the art would achieve adhesion and proliferation of cell by culturing then destroying fibroblast cells. The method should more clearly set for the steps and limitations of the claims such that one of skill in the art would be apprised of the metes and bounds of the claims.

The instant invention is drawn to “a method for adhering or proliferating cell [sic].” It is not clear what cells are being proliferating or to what they are being adhered. The claim as written does not make clear whether the cell in the preamble is the fibroblast cell of the claims or another cell-type entirely.

Claim 2 recites the limitation “separated . . . at least partially.” This limitation is inherently unclear. The limitation provides no floor as to how to measure “partially.” The cell as

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written could read on only one cell in the culture being separated or all but one cell in the culture being separated. Furthermore, there is no guidance in the specification defining "partially." This limitation is an inherently vague phrase and should be clarified.

Claims 4, 6 and 8 recite the limitation "irradiating electromagnetic radiation." This phrase is redundant and should be amended for better clarity.

Claims 5 and 8 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group is indefinite because it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). Applicant recitation of the limitation "at least one selected from the group consisting of" renders it unclear whether the members of the group are mutually exclusive.

Claim 6 recites the limitation "one treatment" in line 2. There is insufficient antecedent basis for this limitation in the claim because there is no recitation indicating that there is a "second treatment" in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US Patent No. 4,016,036) (hereinafter "Green").

The invention of the instant claims is broadly drawn to a method comprising the culturing and destruction of fibroblast cells by freezing, drying or irradiating.

Green discloses a method wherein fibroblast cells are treated to prevent their multiplication in culture. The fibroblast cells are 3T3 cells and are irradiated to eliminate growth and proliferation. See column 1, line 64 and column 2, line 53 through column 3 line 9.

Claims 1-9 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Makitsubo (EP 0 168 217).

The invention of the instant claims is broadly drawn to a method comprising the culturing and destruction of fibroblast cells by freezing, drying or irradiating.

Makitsubo discloses a method wherein fibroblast cells are cultured. The fibroblast cells in culture are then killed. The destroyed fibroblasts are then mixed and incubated with tumor cells. See page 2, lines 12-31 and page 16.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
October 21, 2001



REMY YUCEL, PH.D
PRIMARY EXAMINER